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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/854,906	05/14/2001	Steven F. Sukits	16163-012001	7599

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EXAMINER

BORIN, MICHAEL L

ART UNIT	PAPER NUMBER
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1631

DATE MAILED: 06/15/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/854,906

Applicant(s)

SUKITS ET AL.

Examiner

Michael Borin

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 29 March 2004.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-36 is/are pending in the application.
- 4a) Of the above claim(s) 1-14 and 24-36 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 15-23 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☒ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date _____.
- 4) ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____.
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: _____.

Status of Claims

1. Examiner acknowledges response to restriction requirement filed 11/21/2003 and Sequence Listing filed 03/29/2004.

In response to restriction requirement, applicant elected, without traverse, Group VI, claims 15-23. Claims 1-14, 24-36 are withdrawn from further consideration by the examiner, 37 CFR 1.142(b), as being drawn to a non-elected groups. Cancellation of claims 1-14, 24-36 is requested.

Information Disclosure Statement

2. Applicants' Information Disclosure Statement filed 11/20/2003 has been received and entered into the application. Accordingly, as reflected by the attached completed copies of forms PTO-1449, the cited references have been considered.

3. The listing of references in the specification is not a proper information disclosure statement. 37 CFR 1.98(b) requires a list of all patents, publications, or other information submitted for consideration by the Office, and MPEP § 609 A(1) states, "the list may not be incorporated into the specification but must be submitted in a separate paper." Please, (1) remove the list from specification, and (2) remove numerical numbering of references in the text of specification.

Sequence Listing

4. The Sequence Listing filed 03/29/2004 was approved by STIC for matters of form.

Claim Objections

5. Claims 21-23 are objected to under 37 CFR 1.75(c), as being of improper dependent form for failing to further limit the subject matter of a previous claim. Applicant is required to cancel the claims, or amend the claims to place the claims in proper dependent form, or rewrite the claims in independent form.

Claim Rejections - 35 USC § 102 and 103.

The following is a quotation of 35 U.S.C. § 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103[©] and potential 35 U.S.C. 102(f) or (g) prior art under 35 U.S.C. 103(a).

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6. Claims 15,21-23 are rejected under 35 U.S.C. 103(a) as obvious over Wallach et al (US Patent 6,579,697; effective filing date - 11/12/1996).

Wallach et al describe two types of TNF receptors and their death domain. (TNFR DD). The TNF/NGF superfamily of receptors includes receptors such as the p55 tumor necrosis factor receptors (which is TNFR-1 - see for example Tartaglia et al (IDS, reference ARR) and the FAS ligand receptor. The reference is directed to polypeptides that bind to the intracellular domains of the p55 TNF-R and the FAS-R (designated p55IC, and FAS-IC, respectively) and which polypeptides are capable of modulating the function of the p55 and the FAS-R. One of the polypeptides capable of binding the p55IC of the intact p55-TNF-R is the p55IC itself in the form of a p55IC molecule or a portion thereof, such as for example, the so-called "death domain" (DD) of the p55IC, i.e., death domain of TNRF-1. (See col. 1). Further, the reference describes various uses of information on TNFR death domains, for example, for search of compounds binding to such domains (see columns 16-18) Thus, the reference teaches TNFR-1 death domain, its importance and potential for searching modulators of the domain. Therefore, it would have been *prima facie* obvious to one skilled in the art at the time the invention was made to determine active site(s) of TNFR-1 DD and use this information for identifying agents that can modulate TNFR-1 activity via interaction with the domain.

7. Claims 16-20 (and claims 15, 21-23 if they are amended to recite any particular 3-D coordinates of the death domain) are rejected under 35 U.S.C. 103(a) as obvious over Brunger et al. (Acta Crystallographica, Section D: Biological

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Crystallography (1998), D54(5), 905-921) or Scanlan (US 6236496) alone or in view of Wallach et al (US Patent 6,579,697).

All limitations concerning the type of data are given no patentable weight as they are considered to be non-functional descriptive material. As such, the claim limitations are considered to be limited to a method of identifying agent that interacts with a domain.

Brunger et al. describe a software suite for macromolecular structure determination by X-ray crystallography or nuclear magnetic resonance spectroscopy (i.e. drug design), wherein the software allows users to perform operations on data structures (i.e. electron density maps, atomic properties, etc.) (page 905, column 1, lines 1-5). The authors indicate that the software has been tested on various computers with processors, memory, and graphical display (Figure 1, page 907, column 2, lines 13-16, and page 919, column 1, lines 27-40).

Scanlan et al teach method of computer-aided design of receptor synthetic ligand comprising steps of generating three-dimensional image model of protein comprising a ligand-binding domain and performing modeling of compounds that are capable of interacting with the domain.

The current claims are drawn to method of computer-aided identification of an agent which rely upon particular three-dimensional coordinates of the death domain of TNFR-1. However, as MPEP 2106 notes,

"Nonfunctional descriptive material cannot render nonobvious an invention that would have otherwise been obvious. Cf. In re Gulack, 703 F.2d 1381, 1385, 217 USPQ 401, 404 (Fed. Cir. 1983) (when descriptive material is not functionally related to the substrate, the descriptive material will not distinguish the invention from the prior art in terms of patentability). Common situations involving nonfunctional descriptive material are:

- a computer-readable storage medium that differs from the prior art solely with respect to nonfunctional descriptive material, such as music or a literary work, encoded on the medium,

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- a computer that differs from the prior art solely with respect to nonfunctional descriptive material that cannot alter how the machine functions (i.e., the descriptive material does not reconfigure the computer), or
- a process that differs from the prior art only with respect to nonfunctional descriptive material that cannot alter how the process steps are to be performed to achieve the utility of the invention.

Thus, if the prior art suggests storing a song on a disk, merely choosing a particular song to store on the disk would be presumed to be well within the level of ordinary skill in the art at the time the invention was made. The difference between the prior art and the claimed invention is simply a rearrangement of nonfunctional descriptive material."

In the instant case, the coordinates death domain of TNFR-1 is nonfunctional descriptive material which does not distinguish the invention from the prior art. Therefore, the prior art teaches all of the functional elements of the claims.

Further, it would be obvious to one skilled in the art that methods of Brunger or Scanlan are applicable to identification or design of any receptor ligands of interest. Since Wallach et al demonstrate importance of TNFR-1 death domain, it would be obvious to use structure coordinates of this domain to identify agents interacting with it.

Conclusion.

8. No claims are allowed

9. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Michael Borin whose telephone number is (571) 272-0713. Dr. Borin can normally be reached between the hours of 8:30 A.M. to 5:00 P.M. EST Monday to Friday. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Mr. Michael Woodward, can be reached on (571) 272-0722.

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Any inquiry of a general nature or relating the status of this application should be directed to the Group receptionist whose telephone number is (571) 272-0549.

6/8/04
mlb

MICHAEL BORIN, PH.D
PRIMARY EXAMINER

A handwritten signature in black ink, appearing to read 'Michael Borin', is positioned below the printed name and title.